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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,216	05/31/2001	Robert D. Ainsworth	3764.P003	2384

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EXAMINER	
MANTIS MERCADER, ELENI M	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,216	AINSWORTH ET AL.	
	Examiner	Art Unit	
	Eleni Mantis Mercader	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 3/3/2006 have been fully considered but they are not persuasive. The Examiner used the reference of Engelson'492 to provide evidence that the use of tapered section with a distal plunge-ground length is old in the art. The section of the reference cited by the Examiner is col. 1, lines 41-49 which is a section under "Background of the Invention" clearly indicating what is known as old in the art. That particular section teaches as old that the tapered guidewire increases flexibility, regardless of any drawbacks, and that is the motivation to combine the teachings. The same section references Morrison (US Patent number 4,619,274) which clearly teaches again what is old in the art. Nowhere in the MPEP does it say that you cannot use what is established as old in the art for a rejection, , therefore the portion used from the Engelson still applies. It is not understood why Applicant states that there is no optical fiber since one is cited by the Examiner as element 3. Newly added claims are herein addressed. The optical provides diagnostic information at least during therapy.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-8, 9, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenerz et al. of record in view of Engelson (US Patent 5599492).

3. Claims 1-8, 9, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenerz et al. of record

In regards to claims 1-3, figure l of Tenerz et al. discloses a therapeutic (therefore at least during therapy applies) guidewire having an optical fiber (3) extending along the length of the guidewire for measuring intravascular pressure, column 2. Tenerz et al. furthermore teaches a high strength proximal core section by teaching use of tightly wound wire at the proximal section and flexible distal core by teaching use of flexible, resilient wire at the distal section (see col. 2, lines 25-33).

In regards to claim 4, the teaching to intravascular pressure measurement of Tenerz et al. is an example of hemodynamic blood characteristics.

In regards to claim 5 the references clearly recites that the guidewire is for guiding a catheter, see Abstract. Therefore although the catheter structure is not positively recited in the reference, it is inherent that the guidewire is operatively coupled to a catheter. The sole purpose of having a guidewire is to guide a probe (i.e. catheter) coupled to it. The operative coupling of a catheter to a guidewire is inherent.
ln regards to claim 18 the patent teaches that the components of the guidewire can contain a compound making it visible under radiography or having a radiopaque substance as claimed by applicant, column 3 lines 23-27.

Tenerz et al. furthermore teaches a high strength proximal core section by teaching use of tightly wound wire at the proximal section and flexible distal core by teaching use of flexible, resilient wire at the distal section (see col. 2, lines 25-33).

Tenerz et al. do not explicitly teach a tapered section and a distal plunge-ground length.

In the same field of endeavor, Engelson teaches a tapered section and a distal plunge-ground length because this increases the flexibility of the guidewire where the sharpest wire turns are encountered (see col. 1, lines 41-49).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Tenerz et al. to incorporate the teaching of Engelson in order to allow to increase the flexibility of the guidewire as taught by Engelson.

In regards to claims 6-8, 9, and 22-25 Tenerz et al. teaches an intravascular guidewire having an optical fiber extending thereon for proving blood pressure measurements (example of a hemodynamic characteristic) and further features as stated above.

Tenerz et al. does not expressly teach said optical fiber movable within guidewire and being exposed within vasculature of patient. It would have been obvious to a person of ordinary skill in the art to have a movable optical fiber or a fiber being exposed to the vasculature of the patient because either configuration satisfies the measurement of blood pressure in any desire vascular location as taught Tenerz et al. thereby constituting functional equivalents.

The Tenerz et al. reference does not expressly recite the data processing system and the steps of operating a data processor and processing the diagnostic data. It would have been obvious to a person of ordinary skill in the art to provide said system and method steps of data processing because such is essential to able to read/interpret the diagnostic data received. Any diagnostic and/or therapeutic data received must be feed into appropriate processing means and method for analysis.

4. Claims 11-17, and 19-21 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Tenerz et al in view of Engelson and further in view of Jafari and Hurtak et al of record.

In regards to claims 11-17 and 19-21 Tenerz et al. teaches an intravascular guidewire having an optical fiber extending thereon for proving blood pressure measurements (example of a hemodynamic characteristic).

ln regards to the claims 11 , 15, and 16 Tenerz et al. reference does not expressly teach said optical fiber movable within guidewire and being exposed within vasculature of patient.

It would have been obvious to a person of ordinary skill in the art to have a movable optical fiber or a fiber being exposed to the vasculature of the patient because either configuration satisfies the measurement of blood pressure in any desire vascular Iocation as taught Tenerz et al.

In regards to claims 11-14 and 19-21 Tenerz et al. does not teach specific structure components of guidewire comprising distal core section, proximal core section, connecting member, atraumatic distal tip, flexible coil disposed about distal core section, shaped ribbon coupled to distal core section, atraumatic tip including a metal or polymeric material, and a clear polymeric jacket disposed about distal core section, said clear polymeric jacket coupled to at least one point along an outer surface of the distal core section, the atraumatic distal tip coupled to a distal end of clear polymeric jacket.

Figure 1 of Jafari discloses a therapeutic guidewire (10) comprising an elongated body having a distal core section (12) coupled to a proximal core section (11) by a connecting member (13) and an atraumatic distal tip (24) formed at a distal end (21) of the distal core section (12). The device further

comprises a flexible coil (22) disposed about the distal core section (12) and coupled to at least one point (25) along the distal core section (12). A shaped ribbon (23) is shown within the therapeutic guidewire (10), columns 5-6. The atraumatic distal tip (24) is coupled to the distal end of the flexible coil (22). The atraumatic tip is formed with a solder (includes combination of gold and tin which satisfies applicant's limitation to metal or hardenable polymeric material, column 5, lines 56-61).

The Jafari reference provides evidence that said improved guidewire structure enables advanced access throughout and is easily maneuverable within the vastly branched vascular, column 8 lines 1-29.

It would have been obvious to a person of ordinary skill in the art to incorporate the guidewire structure limitations of Jafari into the system of Tenerz et al. because the structure of Jafari improves on the movement of a guidewire within the vascular of the body.

Tenerz et al. in view of Jafari do not expressly teach a polymeric jacket disposed about the distal core. In the same field of endeavor, Hurtak et al. teach a plastic tip as an alternative to glass or metal as this is a well know functional equivalent material for jackets used with guidewires (see col. 3, lines 60-64).

Therefore, it would have been obvious to one skilled in the art at the time that the invention was made to have modified Tenerz et al. in view of Jafari and incorporated the teaching of Hurtak et al. as an alternative material used in jackets with guidewires.

5. Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tenerz et al. of record in view of Engelson (US Patent 5599492) and further in view of Amundson et al.'346 (US Patent No. 6,178,346).

Tenerz et al. of record in view of Engelson (US Patent 5599492) teach all the elements of the current invention except for the optical fiber conveying an image.

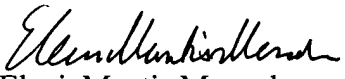
In the same field of endeavor, Amundson et al.'346 teaches the use of an optical fiber for conveying an image in combination with a guidewire (see col. 31, line 40-col. 32, line 29). Therefore, an optical fiber is capable of conveying an image.

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Tenerz et al. in view of Engelson and incorporated the teaching of an opical fiber being used not only as a pressure sensor but also as an imager in order to transmit an image of the area of interest for monitoring while the therapy is ongoing.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM